K102884

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510(k) SUMMARY

JAN 28 2011

Applicant's Name, Address, Telephone, FAX, Contact Person

Advanced Sterilization Products, Division of Ethicon, Inc.
A Johnson & Johnson company
33 Technology Drive
Irvine, CA 92618

Contact Person

Kevin Corrigan, RAC
Director, Regulatory Affairs
Tel: (949) 453-6410
Fax: (949) 789-3900

Summary Date: September 27, 2010

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Biological Sterilization Process Indicator
Common/Usual Name:	Biological Indicator
Product Classification:	II
Proprietary Name:	STERRAD® CYCLESURE® 24 Biological Indicator

2. PREDICATE DEVICES

STERRAD® CycleSure® Biological Indicator, K071014, May 24, 2007

3. INDICATIONS FOR USE

The STERRAD® CYCLESURE® 24 Biological Indicator is intended to be used as a standard method for frequent monitoring of STERRAD® Sterilizer cycles.

4. DESCRIPTION OF DEVICE

STERRAD® CYCLESURE® 24 Biological Indicator is a self-contained stand-alone biological monitor intended for the routine monitoring of the STERRAD® Sterilization Process. It consists of a glass fiber disc containing a minimum of 10^6 CFU of *Geobacillus stearothermophilus* spores, a glass ampoule containing nutrient growth medium, a cap and liner closing the vial and a chemical indicator on top of the cap. The cap contains two small circular openings that allow for diffusion of hydrogen peroxide vapor into the vial. The relatively small size of the circular openings serves as a restriction to this diffusion.

5. SUMMARY OF NONCLINICAL TESTS

The testing conducted demonstrated that our modified STERRAD® CYCLESURE® 24 Biological Indicator device is substantially equivalent to the predicate, unmodified STERRAD® CycleSure® Biological Indicator device. The devices share the same intended

use, utilize the same technology (hydrogen peroxide as sterilant), exhibit the same performance characteristics and those characteristics have been verified using the same test methods for both devices.

Validation Study	Results
Evaporation	Passed
Verification of Positive BI Color	Passed
Bacteriostasis	Passed
Verification of Minimum Incubation Time (Readout)	Passed
Spore Resistance	Passed
BI Validation in STERRAD Sterilizers (Dose Response)	Passed
Growth Promotion	Passed

6. DESCRIPTION OF CHANGE:

The following is a list of the specific changes to the predicate STERRAD® CycleSure® Biological Indicator:

a. Outer vial resin material change (remains molded polypropylene, new vendor)
b. New supplier for silicon coating process for the Tyvek® cap liner
c. Reduced maximum incubation/readout time from 7 days to 3 days
d. Name changed from STERRAD® CycleSure® Biological Indicator to STERRAD® CYCLESURE® 24 Biological Indicator

7. OVERALL PERFORMANCE CONCLUSIONS

The testing conducted demonstrated that the modified STERRAD® CYCLESURE® 24 Biological Indicator device is substantially equivalent to the predicate, unmodified STERRAD® CycleSure® Biological Indicator device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Kevin Corrigan
Director, Regulatory Affairs
Advanced Sterilization Products
33 Technology Drive
Irvine, California 92618

JAN 28 2011

Re: K102884
Trade/Device Name: STERRAD CYCLESURE 24 Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: January 18, 2011
Received: January 19, 2011

Dear Mr. Corrigan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

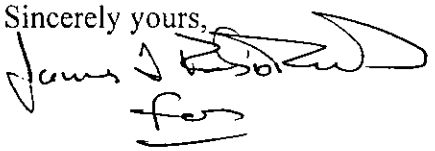
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: STERRAD® CYCLESURE® 24 Biological Indicator

Indications for Use:

The STERRAD® CYCLESURE® 24 Biological Indicator is intended to be used as a standard method for frequent monitoring of the STERRAD® Sterilizer cycles.

Prescription Use _____ AND/OR Over-The-Counter Use ___√___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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